

Remarks

Status of the Claims

Claims 1, 3, 6-35, 40, 46-48, 50, 51, 54-84, and 86-108 are pending in this application, and subject to multiple species elections. Claims 1, 8, 9, 11, 12, 27, 29, 32, 35, 48, 51, 56, 57, 59, 60, 73, 88, 89, 91, 97, 98, 100, 101, 102, 103, and 105 are amended herein and new claims 109-119 are added. In addition, claims 10, 16, 58, and 64 and 104 are cancelled.

Support for the amendment of the claims can be found throughout the specification and the claims as originally filed. Claims 8, 11, 12, 32, 51, 56, 59, 60, 101, and 102 are amended with regard to dependency; claims 9, 27, 29, 56, 73, 88, 91, 98, 103, and 105 are amended as to form; and claims 1, 35, 48, 97, and 100 are amended to remove certain features to other or dependent claims. Specific support for the new claims can be found at least as detailed in the following table.

Claim 110	Original claim 35
Claim 111	Original claim 35
Claim 112	Original claim 35
Claim 113	Original claim 48
Claim 114	Original claim 89
Claim 115	Original claim 97
Claim 116	Original claim 97
Claim 117	Original claim 97
Claim 118	Original claim 97
Claim 119	Original claim 97

After entry of this paper, **claims 1, 3, 6-9, 11-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-119 are pending.**

Telephone Interview

Applicants thank Examiner Nguyen for the telephone interview with Applicants' representative Ian J. Griswold on July 22, 2008. During the telephone interview species election 1 was discussed. The other species rejections were also briefly discussed. Although no formal agreement was reached with regards to the propriety of the species election, Examiner Nguyen agreed to consider arguments in favor of withdrawing species election 1.

Response to Species Election

The Office alleges that there are seven sets of species encompassed by the current claims, and has required election of one species from each set for initial examination. Applicants believe that several of the species elections are improper in view of the subject matter of this invention; it is believed this will be made clear by the amendments and arguments made herein. For clarity, each species election is dealt with individually below. Applicants request that the requirements for species election be withdrawn or modified as discussed below.

Election 1

The Office has required that Applicants elect a single species from amongst the following claim features:

- (a) insertion site(s);
- (b) a single specific encoded heterologous polypeptide recited in the Markush group of claim 10 or claim 58 or claim 104 (which Markush group contains: Sodium iodide symporter (NIS); Nitroreductase (NTR); *E. coli* NTR; Endothelial nitric oxide synthase (eNOS); Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF); and a cytokine)
- (c) an antisense nucleotide; and
- (d) an siRNA.

Solely to comply with 37 CFR 1.146 Applicants provisionally elect **(a) insertion site(s)** with traverse, and with the understanding that the other species will be rejoined when a generic claim is found allowable. Claims 1, 3, 6-9, 11-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-119 read upon this provisionally elected species.

Election between these alleged species is traversed as improper at least because it requires election between combination(s) and a subcombination. Election of part (a) results in subcombination claims directed to a nucleic acid vector comprising...one or a plurality of insertion sites, while election of one of parts (b) through (d) results in combination claims directed to a nucleic acid vector comprising... “a third nucleic acid of interest” which itself can be any of (b) through (d). To further emphasize this distinction, claims 1, 42, 89 and 97 are amended herein to remove the “nucleotide sequence of interest”; this feature is now recited in claims that depend from claims 1, 42, 89 and 97 (claims 109, 113, 114, and 115 respectively). Claims 109, 113, 114 and 115 recite that the nucleotide of interest is **inserted into the insertion**

site recited in claims 1, 42, 89 and 97, respectively. Therefore claims in which any of parts (b) through (d) are elected are a combination that includes all of the features of the claim if part (a) is elected; and might be designated by the combination of component “AB + C” while the designated species (a) might be designated by the combination of components “AB.” Applicants request first that the Office acknowledge the combination/subcombination status of the alleged species of this election.

While requirement for election between a combination and a subcombination may be proper under certain circumstance (which circumstances are not conceded in this case), MPEP 806.05(c) explains:

Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104.

Because the claimed subject matter when part (a) is elected is a subcombination of the subject matter claimed if one of parts (b) – (d) is elected, these four elements do not represent genera for which a species election can be made and the species election is improper. Applicants respectfully request that the Office modify or withdraw species election 1.

If this election is modified or withdrawn, Applicants would still elect to initially prosecution claims encompassing “insertion site(s)”. However, Applicants understand that the Office may require election of one of the “nucleic acid sequence[s] of interest” as encompassed by (b) through (d) above. If this is necessary, Applicants elect (b), and more particularly Granulocyte Macrophage Colony-Stimulating Factor (GM-CSF) for initial prosecution, with traverse. Claims 1, 3, 6-9, 12-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-104, 106-119 would read upon this elected species, if such election is necessary.

Election 2

The Office has required that Applicants elect a single species from amongst (a) a ribosome binding site; (b) a constitutive promoter; and (c) an inducible promoter. Applicants

elect **a ribosome binding site** for initial examination with the understanding that the other species will be rejoined when a generic claim is found allowable. Claims 1, 3, 9, 11-15, 17-35, 40, 46-48, 50, 51, 56, 57, 59-63, 65-84, and 86-119 read upon the elected species.

Election 3

The Office has required that Applicants elect a single insertion site or a specific combination of insertion sites recited in the Markush group of claim 16 or claim 64 (which Markush group contains: ClaI, BglII, NruI and XhoI restriction endonuclease sites). Claims 16 and 64 are cancelled herein, rendering the election of species moot.

Election 4

The Office has required that Applicants elect a single species from amongst (a) GFP; (b) EGFP; and (c) a defined nucleotide sequence detectable by hybridization.... Applicants elect **GFP** for initial examination with the expectation that the other species will be rejoined when a generic claim is found allowable. Claims 1, 3, 6-9, 11-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-119 read upon the elected species.

Election 5

Election 5 requires that Applicants elect a single specific herpes simplex virus recited in the alleged Markush group of claim 35 (which Markush group contains: a gene specific null mutant, an ICP34.5 null mutant, lacks only one expressible ICP34.5 gene, non-neurovirulent, and a combination of two or more thereof). Solely to comply with 37 CFR 1.146, Applicants elect **a gene specific null mutant** with traverse, and with the understanding that the other species will be rejoined when a generic claim is found allowable. Claims 1, 3, 6-9, 11-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-119 read upon the provisionally elected species.

Applicants traverse this species election because it is improper to require a species election between non-mutually exclusive features such as the listed herpes simplex viruses. As explained in MPEP 806.04(f):

“a requirement for restriction to a single species may be proper if the species are mutually exclusive. Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope.” [emphasis added]

The features alleged to define the species of election 5 are not mutually exclusive, they overlap in scope, and the species election is therefore improper. For example, alleged species “a gene specific null mutant” overlaps in scope with alleged species “an ICP34.5 null mutant”(which is an example of a gene specific null mutant) and a virus that lacks only one expressible ICP34.5 gene (as this also is encompassed in the term “gene specific null mutant”). In another example, alleged species “an ICP34.5 null mutant” overlaps with alleged species “a non-neurovirulent herpes simplex virus”, because (as explained in the specification page 2, lines 25-32) an ICP34.5 null mutant is a non-neurovirulent herpes simplex virus.

To further illustrate the non-mutually exclusive nature of these features, claim 35 is rewritten as a series of claims dependent upon claim 32 (see claims 35 and 110-112), each of which is drawn to a single of the alleged species. Because the alleged species overlap in scope the species election is improper and Applicants request that it be withdrawn.

Election 6

Election 6 requires that Applicants elect one of the herpes simplex virus strains listed in the Markush group in claim 76 (which Markush group contains: HSV-1 strain 17, HSV-1 strain F and HSV-2 strain HG52). Applicants elect **HSV-1 strain 17** for initial examination, with the understanding that the non-elected species will be rejoined upon allowance of a generic claim. Claims 1, 3, 6-35, 40, 46-48, 50, 51, 54-84, and 86-119 read upon the elected species.

Election 7

Election 7 requires that Applicants elect a single specific or single combination of additional steps recited in claim 100 (which additional steps are: screening said co-transfected cell culture to detect mutant HSV expressing said marker, isolating said mutant HSV, screening said mutant HSV for expression of the nucleotide sequence of interest or the RNA or polypeptide

thereby encoded, screening said mutant HSV for lack of an active gene product, testing the oncolytic ability of said mutant HSV to kill tumour cells *in vitro*, or a combination of two or more thereof). Solely to comply with 37 CFR 1.146, and with the understanding that the other species will be rejoined when a generic claim is found allowable, Applicants provisionally elect with traverse the additional step species **screening said co-transfected cell culture to detect mutant HSV expressing said marker**. Claims 1, 3, 6-9, 11-15, 17-35, 40, 46-48, 50, 51, 54-57, 59-63, 65-84, and 86-119 read upon the read upon the provisionally elected species.

Applicants traverse this species election because, as explained above with respect to Election 5, it is improper to require a species election between non-mutually exclusive features. To further illustrate that the alleged species set forth in Election 7 are non-mutually exclusive, claim 100 has been rewritten as a series of claims dependent upon claim 97 (see claims 100 and 115-118). The steps recited in claims 100 and 115-118 are non-mutually exclusive because any combination of these steps can be practiced. For example, alleged species “screening said co-transfected cell culture to detect mutant HSV expressing said marker”, and alleged species “screening said mutant HSV for expression of the nucleotide sequence of interest or the RNA or polypeptide thereby encoded” can be practiced in the same method. Similarly alleged species “isolating said mutant HSV” can be practiced with any of the other additional method steps. Because the alleged species are not mutually exclusive they do not define genera from which a species election can be required. Species Election 7 is improper and Applicants request that it be withdrawn.

In accord with 37 CFR §1.143, Applicants specifically reserve the right to petition any and all of the above species elections, if any are maintained in spite of this response. Applicants also request that any non-elected species be rejoined should generic claims be allowed.

Conclusion

Applicants believe that the present claims are in condition for substantive examination, and such action is requested. The Examiner is invited to call the undersigned if the Examiner believes that a telephone interview would facilitate substantive examination of this application.

Respectfully submitted,

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